

REMARKS

Claims 1, 4, 6-7, 9-16, 18-23, 49, 61-65, 67-68, 70-71, 73-77, 79 and 81-82 are pending. The Examiner has rejected claims 1, 4, 6, 7, 9-16, 18-23, 49 and 61-82. Reconsideration and withdrawal of all rejections is respectfully requested in view of the above-provided amendments and the following remarks.

The Application is After Final. The above-provided amendments include elements that were either previously before the Examiner, or were made at the suggestion of the Examiner, to place the application into condition for allowance. Thus, it is urged to be within the discretion of the Examiner to enter the above-provided amendments.

AMENDMENTS TO THE CLAIMS

Claims 1, 4, 13-14, 18, 79 and 81-82 are amended, without prejudice, to insert "isolated" with respect to the subject recombinant polypeptide. This is supported by the specification and the previously pending claims. Claim 13 is amended to replace "purified" by "isolated" in the preamble simply for consistency with claims 1, 4, 14, 79 and 81-82.

Claim 18, *et seq.* are amended to replace the term "vaccine" with "immunogenic composition," without prejudice. This amendment was suggested by the Examiner at page 8 of the Office Action, and is supported, for example, at page 8, lines 14-16 and 19-25, and page 22, lines 29-30 of the specification.

An informality in the spelling of "Gln" is corrected in claim 82(7).

The dependencies of several claims have been amended to provide proper antecedent basis, and claims 66, 69, 72, 78, 80 have been newly cancelled, without prejudice.

No new matter is added.

THE TELEPHONE INTERVIEW

Applicants' undersigned attorney expresses his appreciation for the courtesy of a telephone interview granted by the Examiner on November 4, 2009. During the telephone interview the formal grounds for rejection and objection were discussed. Agreement was reached that the amendments provided herewith should place the claims into condition for allowance. The details of the amendments and how they overcome the grounds of rejection and

objection, are provided in the following remarks.

**THE CLAIMS COMPLY WITH THE
WRITTEN DESCRIPTION REQUIREMENT
UNDER 35 U.S.C. § 112, FIRST PARAGRAPH**

At item 7 (pages 3-8) of the Office Action, the Examiner has maintained the previous rejection of claims 18-23, 49 and also has rejected newly added claims 64-78 under 35 U.S.C. § 112, first paragraph, as allegedly not enabled (written description) by the specification. The Examiner bases this rejection on the use of the term, "vaccine" in the rejected claims.

Applicants respectfully disagree. While there is no precise definition of "vaccine" in the specification, it is respectfully submitted, for all of the reasons provided in the previous response, dated March 16, 2009, incorporated by reference herein, that the subject compositions would be readily understood and appreciated by the ordinary artisan to be vaccines as conventionally understood in the art. However, in order to expedite the prosecution of the application for business purposes, the Applicants have amended the claims in view of the Examiner's statement in the instant Office Action, at page 8, last paragraph, as quoted below.

Amendments to the instant claims to recite "immunogenic composition" instead of "vaccine" will obviate the instant rejection and Applicants are enabled for a method of protecting salmonid fish from salmonid rickettsial septicemia disease wherein the occurrence of infection by *P. salmonis* is delayed and mortality due to *P. salmonis* infection is reduced by administering any of the immunogenic compositions set forth above.

With these amendments, it is respectfully urged that this ground of rejection is now obviated. For all of these reasons, reconsideration and withdrawal of this ground of rejection is respectfully requested.

OBJECTION TO THE CLAIMS IS OBLIVIATED

At item 8 of the Office Action (page 9), claims 71-72 are objected to under 37 CFR 1.75 as being a substantial duplicate of claim 70. Claim 71 is now amended to depend from claim 65, and claim 72 is cancelled, without prejudice, as duplicative of amended claim 71. This is submitted to obviate this ground of objection.

At item 9 of the Office Action (pages 9-10), claim 80 is objected to under 37 CFR 1.75 as allegedly a substantial duplicate of claim 6. The Examiner reasons that "consisting essentially

of" as employed in claim 80, and as defined by the specification, has the same scope and meaning as does "comprising" as employed in claim 6. Claim 80 is now cancelled, thus obviating this ground of objection.

For all of these reasons, reconsideration and withdrawal of these grounds of objection is respectfully requested.

**THE CLAIMS ARE DIRECTED TO
PATENTABLE SUBJECT MATTER UNDER 35 U.S.C. § 101**

At item 10 of the Office Action (pages 10-11), claims 1, 4, 6, 7, 9-16, 18-23, 49 and 61-82 are rejected under 35 U.S.C. § 101 as allegedly directed to non-statutory subject matter. The Examiner took the position that the term, "isolated" must be inserted into the polypeptide claims to differentiate the subject polypeptide from that found in nature. We disagree with the Examiner's conclusion that a man made recombinant polypeptide having a specified sequence, as recited by claim 1, falls under the natural product exemption to patentable subject matter.

After discussion with the Examiner during the telephone interview, it was agreed that "recombinant" is sufficient to avoid this rejection under 35 U.S.C. 101. Nevertheless, Applicants now reinsert the term "isolated" into the polypeptide claims for additional clarity. However, it should be noted that claim 11, directed to "a method for producing a ^{Ps}p45 recombinant polypeptide..." is not amended to include "isolated", since the nature of the method as recited would make that requirement inappropriate.

In addition, the nucleic acid claims are kept as before, reciting "isolated or recombinant" since it is understood from the telephone interview that either "isolated" or "recombinant" will show the hand of man for purposes of confirming patentable subject matter under 35 U.S.C. 101.

For all of these reasons, reconsideration and withdrawal of this ground of rejection is respectfully requested.

**THE CLAIMS ARE ENABLED UNDER
35 U.S.C. § 112, FIRST PARAGRAPH**

At item 11 of the Office Action (pages 11-16), claims 79-82 are rejected under 35 U.S.C. § 112, first paragraph, for allegedly failing to comply with the written description requirement.

Claims 79-82 are directed to, "[a] ^{Ps}p45 recombinant polypeptide that consists essentially of at least 95% of the amino acid sequence of..." the respective sequence listings. At page 12 of the Office Action, the Examiner took the position that the definition of "consisting essentially of" provided by the specification (page 17) requires retention of an important characteristic of the ^{Ps}p45 protein and that the specification does not teach how to make a polypeptide that retains this property with "at least 95% of" the respective sequence listings.

Applicants respectfully disagree. To begin, claim 80 is cancelled, thus obviating this ground of rejection as to claim 80. Further, it is submitted that the ordinary artisan would know, from reading the specification, how to make that which was originally claimed. However, in the interest of expeditious prosecution, and after discussion with the Examiner during the telephone interview, claims 79 and 81-82 are now amended, without prejudice, to remove the ^{Ps}p45 designation and to replace "consisting essentially of" by "comprising." During the telephone interview, the Examiner agreed that, with these changes, and in view of the guidance and analysis provided by the Written Description Guidelines of March 2008 (revision 1) published by the Patent Office, the polypeptides of claims 79 and 81-82 are fully supported by the written description of the application.

For all of these reasons, reconsideration and withdrawal of this ground of rejection is respectfully requested.

**THE CLAIMS ARE ENABLED UNDER
35 U.S.C. § 112, FIRST PARAGRAPH**

At item 12 of the Office Action (pages 16-22), claims 79-82 are rejected under 35 U.S.C. § 112, first paragraph, for allegedly not being enabled by the specification. The Examiner took the position that the specification did not teach how to make and use the invention with the scope as claimed.

Applicants respectfully disagree. As noted above, claim 80 is cancelled, thus obviating the rejection as to this claim. In addition, claims 79 and 81-82 are amended, as indicated. During the telephone interview, it was agreed that the specification did enable the claimed variant polypeptides, by providing preferred conserved amino acid exchanges (substitutions). These are found in the specification at page 26, lines 14-22, and are also recited by claim 82. It is submitted that the ordinary artisan, who has read the instant patent application, will be able to

prepare a polypeptide according to claims 79 and 81-82 without undue experimentation.

For all of these reasons, reconsideration and withdrawal of this ground of rejection is respectfully requested.

**THE CLAIMS ARE DEFINITE
UNDER 35 USC 112, SECOND PARAGRAPH**

At item 13 of the Office Action (page 23), claims 66, 69 and 78 are rejected under 35 U.S.C. § 112, second paragraph, for a lack of antecedent basis in claim 61. Claim 66 is cancelled as duplicative of claim 65, as are claims 69 and 78 that depend from claim 66. This is submitted to obviate this ground of rejection.

For all of these reasons, reconsideration and withdrawal of this ground of rejection is respectfully requested.

CONCLUSION

The claims are urged to be in condition for allowance, and early action to that end is respectfully requested. If any questions remain, the Examiner is respectfully requested to contact the undersigned by telephone to resolve any such questions.

No fees are believed to be required for entry of this Response. However, in the event that it is determined that any fee is due, or any extension of time is required, the Commissioner is authorized to treat this paper as authorizing payment of any such fee, or to treat this paper as the required petition for extension of time, and to charge any required fee to Deposit Account No. 02-2275.

Respectfully submitted,

LUCAS & MERCANTI, LLP



Laurence Manber
Registration No. 35,597

LUCAS & MERCANTI, LLP
475 Park Avenue South
New York, New York 10016

Phone: 212-661-8000
Fax: 212-661-8002